**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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| In re Application of: | Group Art Unit: 1723 |
| GOOD, Thomas J. | Examiner: Kim, Sun U |
| Serial No.: 10/088,330 | |
| Filing Date: December 30, 2003 | |
| For: Microcolumn For Extraction Of Analytes From Liquids | |

## DECLARATION -- RULE 1.132

I, Thomas J. Good, declare that I am the founder, President and Chief Executive Officer of CERA, Inc. (CERA) and have been in the employ of CERA since it's incorporation in 1987 and in the present capacity as an officer since the incorporation of CERA in 1987. I am also a named inventor of the above-referenced patent application. The following is known to me personally, and, if called to testify thereto, I could and would do so.

CERA, Inc. is a manufacturer of unique and innovative solid phase extraction products including microcolumns for the extraction of analytes from liquid samples.

I am familiar with the above-referenced patent application, as well as the development, usages and properties of microcolumns for the extraction of analytes from liquid samples. CERA is presently using the invention claimed in the above-referenced patent application to manufacture microcolumns for separating analytes and other substances from liquid samples. The claimed apparatus, i.e., a microcolumn, has enjoyed a wide degree of acceptability as it provides solutions to many extraction problems that require a high degree of purification and efficient processing.

## BACKGROUND INFORMATION

Accurate and inexpensive analyte detection is important in health care, such as for monitoring the health of patients through blood and urine analysis, and for other laboratory

settings, such as for monitoring the use of illegal or restricted drugs.

Solid phase extraction is a chromatographic technique used to concentrate a sample, or to isolate an analyte (or target substance) of interest by removing impurities and other interfering substances that may be present in the sample. This is done by selectively separating the analyte from the liquid sample on a separation media, either by keeping the analyte of interest and washing off the impurities (followed by elution of the analyte), or by retaining the impurities and eluting the analyte of interest. After the analyte is removed from the separation media, tests may be conducted to qualify and/or quantify (i.e., detect) the analyte.

Prior art extraction columns, such as those described in Mehl (US Pat. No. 4,774,058) typically use a separation media having a larger particulate diameter, e.g., in the 40 μm range. Extraction columns such as these generally employ larger sized separation media because of the difficulty in packing microparticulate separation media, e.g., separation media having a diameter of less than 20 μm, into a microcolumn. Packing microparticulate separation media into a column is difficult due to the volatile nature of dry microparticulate separation media, which has a texture and particle size comparable to talc. Attempts to overcome the problems associated with packing microparticulate separation media into a column include embedding the separation media into a matrix of PTFE, such as described in US Pat. No. 5,279,742 (Markell et al.).

CERA fully appreciated and had an interest and desire in manufacturing an extraction column that was fast and removed a high percentage of analyte from a sample, and minimized the sample volume and wash eluent liquid necessary to extract the analtye from the sample. With the invention of an extraction column having a thin layer of microparticulate extraction media where the extraction media has a particle size of less than 20 microns, according to the above-referenced patent application, CERA was able to manufacture an extraction column meeting the above specifications.

## COMMERCIAL SUCCESS

CERA's claimed invention overcomes the shortcomings of existing extraction

column on the market. Due to the combination of the thin layer of microparticulate extraction media and the compression layers, rapid extraction of an analyte from a sample can be obtained, with sample volumes of less than .5 ml and eluent liquid volumes of around .5 to .75 ml. In addition, the extraction device of the claimed invention is inexpensive to use and manufacture, is stable during storage and transportation, and is compatible with existing automated equipment.

For a number of years in a highly competitive field, there was a long-felt want and unsupplied need for an inexpensive device, i.e., an extraction column having microparticulate separation media (i.e., less than 20 microns). Because CERA's extraction columns satisfy this long-felt want and need, CERA's products have enjoyed substantial commercial success since their introduction and are expected to continue to do so.

In my opinion, the product of the claimed invention is not obvious, notwithstanding the great need for a successful extraction column having microparticulate separation media. It was not until I and the other inventors of this invention produced the successful extraction column, that an extraction column having microparticulate separation media became a practical reality.

In my opinion, the commercial success of CERA's extraction columns, produced according to the claimed invention, has resulted from advantages not found in other extraction columns known to me. These advantages are that CERA's devices have within the apparatus container (1) a passage having a thin layer of microparticulate extraction media (less than 20 microns) for extracting a substance; and (2) upper and lower compression layers that press the extraction media therebetween. Utilizing these features, CERA's extraction columns are able to obtain uniform flow of sample and eluent fluids through the extraction media. This results in high extraction yields with minimum elution volumes.

As a result of these advantages, the extraction columns, produced according to the claimed invention, have been commercially successful since their introduction in May of 1996. Since their introduction, CERA has sold over 5 million columns in the United States. CERA produces all the microcolumns sold in the industry having a separation media of less than 20

microns, having the entire market share for this patented invention.

In addition, scientists in the field have recognized the superiority of CERA's extraction columns. I am attaching a list of articles which use CERA extraction columns to perform analyte extractions. The full text of these articles can be provided upon request.

In my opinion, the commercial success that we have enjoyed in our sales of the claimed products is primarily attributable to the advantages of the product since no extensive amount of advertising was conducted. Further, CERA did not have a position as a market leader before the introduction of the claimed products and CERA does not produce instrumentation that requires the use of the claimed products or ties the consumer to the use of the claimed products. There are competing products on the market (i.e., microcolums having larger sized separation media (i.e., larger than 20 microns, or differently configured microcolumns) that consumers are free to choose from. The commercial success enjoyed by CERA in selling the claimed products is an indication that the elements and composition of the claimed apparatus attests to its usefulness and should have relevancy as indicia of non-obviousness of the invention.

I declare that all statements made herein of my own knowledge are true and all statements made on information or belief are believed to be true, and further, that the statements herein were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code and that such wilful false statements may jeopardize the application or document or any patent resulting therefrom.

Executed this 19th day of April, 2006 at Baldwin Park, California.

Thomas J. Good